ARC 0572C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136A.8, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 4, "Center for Congenital and Inherited Disorders," Iowa Administrative Code.

The proposed amendments describe the responsibilities of the state genetics coordinator; add a heading for the Congenital and Inherited Disorders Advisory Committee and incorporate the Committee's current bylaws into the rules; update definitions; update acronyms; rename the Neonatal Metabolic Screening Program to reflect the broader scope of testing available; increase the newborn screening fee due to a recently approved addition to the newborn screening panel; and eliminate the requirement that a sliding fee scale be used for the billing of services provided through the Regional Genetics Consultation Services and the Neuromuscular and Related Diseases clinics. Finally, the proposed amendments seek to clarify services provided through congenital and inherited disorders programs.

These proposed amendments have been reviewed by the Congenital and Inherited Disorders Advisory Committee and interested individuals within the field.

Any interested person may make written comments or suggestions on the proposed amendments on or before February 12, 2013. Such written comments should be directed to Kimberly Piper, State Genetics Coordinator, Center for Congenital and Inherited Disorders, Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319; fax (515)242-6013. E-mail may be sent to kimberly.piper@idph.iowa.gov.

An opportunity to receive public comment will be held by conference call on February 12, 2013, from 9 to 10 a.m. Those wishing to participate in the conference call at any point during that time may dial 1-866-685-1580, then, when prompted, enter pass code 5152816466, followed by the pound sign (#). If problems occur, please contact Patrick Goebel at 1-800-383-3826.

Any persons who intend to attend the public hearing and have special requirements, such as those related to hearing impairments, should contact the Department of Public Health and advise staff of specific needs.

After analysis and review of this rule making, the impact on jobs is anticipated to be minimal.

These amendments are intended to implement Iowa Code chapter 136A.

The following amendments are proposed.

ITEM 1. Amend rule 641—4.1(136A) as follows:

641—4.1(136A) Program ~~explanation~~ overview. The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa ~~neonatal metabolic~~ newborn screening program, expanded maternal serum alpha-fetoprotein screening program, regional genetic consultation service, neuromuscular and related genetic disease program and Iowa registry for congenital and inherited disorders.

4.1(1) *Advisory committee.* The center for congenital and inherited disorders advisory committee represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director of the department of public health regarding issues related to genetics and hereditary and congenital disorders and makes recommendations about the design and implementation

of the center's programs. ~~Committee membership is made up of representatives of professional groups, agencies, legislators, consumers and individuals with an interest in promoting genetic services for the residents of Iowa.~~

4.1(2) *Genetics coordinator.* The state genetics coordinator assigned within the department provides administrative oversight to the center for congenital and inherited disorders program within Iowa.

4.1(3) *Title V.* The center for congenital and inherited disorders has an association with the state Title V maternal child health program to promote comprehensive services for women, infants and children.

ITEM 2. Rescind the definitions of "Birth center" and "Tandem mass spectrometry" in rule **641—4.2(136A)**.

ITEM 3. Adopt the following **new** definition in rule **641—4.2(136A)**:

"Primary health care provider" means a licensed physician, physician assistant, nurse practitioner, or certified nurse midwife providing primary medical care to a patient.

ITEM 4. Amend the following definitions in rule **641—4.2(136A)**:

"Anonymized specimen" means a specimen that cannot be traced back to or linked with the particular ~~infant~~ individual from whom the specimen was obtained. ~~Specimens shall be anonymized by removing the dried blood spot portion from the infant information portion of the specimen collection form.~~

"Birthing ~~hospital~~ facility" means a private or public ~~hospital~~ facility licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Central laboratory" means the ~~University Hygienic Laboratory~~ state hygienic laboratory (~~UHL~~ SHL), which is designated as the screening laboratory to perform testing and reporting for the Iowa ~~neonatal metabolic~~ newborn screening and Iowa maternal prenatal screening programs.

"Consulting physician" means a physician designated by the center for congenital and inherited disorders to interpret ~~test~~ screen results and provide consultation to a licensed health care provider.

"Discharge" means a release of an infant from a hospital ~~to the infant's parent or legal guardian~~ or birth center.

"Follow-up program" means the ~~designated individuals from the divisions of endocrinology, hematology, pulmonology and medical genetics of the department of pediatrics of the University of Iowa~~ services provided to follow up on an abnormal screening result.

"Health care provider" means a licensed physician, nurse practitioner, certified nurse midwife, registered nurse, or physician assistant providing medical care to an individual.

"Iowa maternal prenatal screening program" or *"IMPSP"* means a program that provides a screening test designed to identify women with an increased risk of having a baby with a congenital or inherited disorder or women at risk of developing a problem later in pregnancy.

"Receiving ~~hospital~~ facility" means the ~~hospital~~ facility receiving an infant from a birthing ~~hospital~~ facility.

"Residual ~~neonatal metabolic~~ newborn screening specimen" means the portion of the specimen that may be left over after all activities necessary for the Iowa ~~neonatal metabolic~~ newborn screening program are completed.

"Transferring ~~hospital~~ facility" means the birthing ~~hospital~~ facility that transfers the infant to another ~~hospital~~ facility.

"~~University~~ State hygienic laboratory" or *"~~UHL~~ SHL"* means the designated central testing laboratory.

ITEM 5. Amend rule 641—4.3(136A), introductory paragraph, as follows:

641—4.3(136A) Iowa ~~neonatal metabolic~~ newborn screening program (~~INMSP~~ INSP). This program provides comprehensive ~~neonatal metabolic~~ newborn screening services for hereditary and congenital disorders for the state ~~to allow children and their families the earliest possible opportunity to receive appropriate early intervention services~~. ~~The program includes the following: birthing hospitals, birth centers, health care providers, UHL, follow-up consultants, and consulting physicians.~~

ITEM 6. Strike "birthing hospitals or birth centers" wherever it appears in paragraph **4.3(1)"c"** and insert "birthing facilities" in lieu thereof.

ITEM 7. Amend paragraphs **4.3(2)"b"** and **"c"** as follows:

b. Waiver. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening waiver. The birthing ~~hospital, birth center,~~ facility or attending health care provider shall ~~notify~~ submit the signed refusal of screening waiver to the central laboratory ~~of the waiver~~ within six days of the refusal.

c. Collection of specimens. A filter paper blood specimen shall be collected from the infant between 24 to 48 hours after the infant's birth~~; however, a specimen collected up to five days after the infant's birth is valid~~. A specimen shall not be collected from an infant less than 24 hours after birth except as follows:

(1) A blood specimen must be collected before any initial transfusion, even if the infant is less than 24 hours old.

(2) No change.

ITEM 8. Strike the acronym "UHL" wherever it appears in paragraph **4.3(2)"d,"** subrule **4.3(5)**, and paragraphs **4.3(6)"c," 4.3(8)"a"** and **4.3(10)"e"** and insert "SHL" in lieu thereof.

ITEM 9. Rescind paragraph **4.3(2)"e"** and adopt the following **new** paragraph in lieu thereof:

e. Waiver for the release of residual specimens for research use. The department shall establish policies and procedures, including a refusal for research waiver form, to allow a parent or guardian the ability to refuse the release of the newborn's residual newborn screening specimen for research purposes. The birthing facility or attending health care provider shall submit the signed refusal for research waiver to the central laboratory pursuant to established policy and procedure.

ITEM 10. Rescind paragraph **4.3(2)"f."**

ITEM 11. Strike "neonatal metabolic screening" wherever it appears in subrules **4.3(3)** to **4.3(5)**, **4.3(7)** and **4.3(8)** and insert "newborn screening" in lieu thereof.

ITEM 12. Amend subrule 4.3(3), catchwords, as follows:

4.3(3) ~~*Health*~~ *Primary health care provider responsibility.*

ITEM 13. Amend paragraph **4.3(3)"a"** as follows:

a. The ~~licensed attending~~ health care provider shall ensure that infants under the provider's care are screened.

ITEM 14. Strike "birthing hospital or birth center" wherever it appears in subrule **4.3(4)** and insert "birthing facility" in lieu thereof.

ITEM 15. Amend subparagraph **4.3(4)"c"(2)** as follows:

(2) If the infant is transferred ~~out of house~~ to another facility within the state, the birthing ~~hospital or birth center~~ facility shall notify the receiving ~~hospital~~ facility of the status of the ~~neonatal metabolic~~ newborn screening. The receiving ~~hospital~~ facility shall then be responsible for completion of the ~~neonatal metabolic~~ newborn screening prior to discharge of the infant.

ITEM 16. Amend subparagraph **4.3(4)"d"(1)** as follows:

(1) The infant is discharged or transferred to another ~~hospital~~ facility before the infant is 24 hours old.

ITEM 17. Strike "Iowa neonatal metabolic screening program" and "INMSP" wherever they appear in subrules **4.3(5)**, **4.3(7)**, and **4.3(10)** and rule **641—4.7(136A)** and insert "Iowa newborn screening program" and "INSP," respectively, in lieu thereof.

ITEM 18. Amend paragraphs **4.3(5)"b"** and **4.3(5)"d"** to **"h"** as follows:

b. Contact all birthing ~~hospitals and birth centers~~ facilities to inform them of the courier schedule.

d. Notify the submitting health care provider, birthing ~~hospital, birth center~~ facility, or drawing laboratory of an unacceptable specimen and the need for another specimen.

e. Report a presumptive positive ~~test~~ screen result within 24 hours to the consulting physician or the physician's designee.

f. Distribute specimen collection forms, specimen collection procedures, ~~screening waivers~~ refusal of newborn screening forms, and other materials to drawing laboratories, birthing ~~hospitals, birth centers~~ facilities, and health care providers.

g. Report normal and abnormal screening results to ~~birthing hospitals, birth centers, or drawing laboratories~~ the submitting facility or provider.

h. Submit a written annual report of the previous ~~fiscal~~ calendar year to the center by ~~September 30~~ July 1 of each year. This report shall include:

(1) to (7) No change.

ITEM 19. Amend subrule 4.3(6), introductory paragraph, as follows:

4.3(6) *Follow-up program responsibility.* ~~Under the direction of consulting physicians, metabolic, endocrine, pulmonary and hemoglobinopathy follow-up~~ Follow-up programs shall be available for all individuals identified by the ~~metabolic~~ newborn screening as having an abnormal screen result.

ITEM 20. Amend paragraphs **4.3(6)"a"** and **"b"** as follows:

a. The follow-up activities shall include care coordination, consultation, recommendations for treatment when indicated, case management, education and quality assurance.

b. The follow-up programs shall submit a written annual report of the previous ~~fiscal~~ calendar year by ~~September 30~~ July 1 of each year. The report shall include:

(1) to (6) No change.

ITEM 21. Amend subparagraph **4.3(7)"b"(2)** as follows:

(2) A ~~local~~ primary health care provider, birthing ~~hospital, birth center~~ facility, or submitting laboratory.

ITEM 22. Amend subparagraph **4.3(7)"b"(4)** as follows:

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department ~~and the state board of health~~.

ITEM 23. Amend paragraph **4.3(8)"a,"** introductory paragraph, as follows:

a. A ~~neonatal metabolic~~ newborn screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing ~~hospital, birth center,~~ facility or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form.

ITEM 24. Amend subrule 4.3(9) as follows:

4.3(9) ~~*INMSP*~~ *INSP fee determination.*

a. The department shall annually review and determine the fee to be charged for all activities associated with the ~~INMSP~~ INSP. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year. The ~~neonatal metabolic~~ newborn screening fee is ~~$112~~ $122.

b. The department shall include as part of this fee an amount determined by the committee and department to fund the provision of special medical formula and foods for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the program.

ITEM 25. Strike the acronym "UHL" wherever it appears in subrules **4.4(1)**, **4.4(2)**, **4.4(4)** and **4.4(7)** and insert "SHL" in lieu thereof.

ITEM 26. Amend subrule 4.4(1) as follows:

4.4(1) *Maternal screening policy.* It shall be the policy of the state of Iowa that all pregnant women are offered ~~the Iowa~~ maternal prenatal screening. The Iowa maternal prenatal screening program provides a risk assessment for open neural tube defects, ventral wall defects, Down syndrome, and Trisomy 18.

a. and *b.* No change.

ITEM 27. Amend paragraph **4.4(2)"c"** as follows:

c. Reporting of abnormal results. Abnormal ~~test~~ screen results shall be reported within 24 hours to the consulting physician or the physician's designee who shall then notify the ~~submitting~~ primary health care provider. On the next working day, this initial report shall be followed by a written report to the ~~submitting~~ primary health care provider.

ITEM 28. Amend subrule 4.4(3) as follows:

4.4(3) *Consulting physician responsibility.* A consulting physician shall be designated by the center in collaboration with the ~~UHL~~ SHL to provide interpretation of ~~test~~ screen results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal ~~test~~ screen results, assist with questions about management of identified cases, provide education and assist with quality assurance measures. The screening program, with assistance from the consulting physician, shall:

a. In collaboration with the ~~UHL~~ SHL, submit a proposed budget and narrative justification for the upcoming fiscal year to the center by January 31 of each year, and

b. Submit a written annual report of the previous ~~fiscal~~ calendar year to the center by ~~September 30~~ July 1 of each year. The report shall include:

(1) to (6) No change.

ITEM 29. Amend subparagraph **4.4(6)"b"(2)** as follows:

(2) A ~~local~~ primary health care provider~~,~~ or submitting laboratory.

ITEM 30. Amend rule 641—4.5(136A), introductory paragraph, as follows:

641—4.5(136A) Regional genetic consultation service (RGCS). This program provides comprehensive genetic and genomic services statewide through outreach clinics.

ITEM 31. Amend subrule 4.5(1) as follows:

4.5(1) *Provision of comprehensive genetic and genomic services.* The department shall contract with the division of medical genetics within the department of pediatrics at the University of Iowa to provide genetic and genomic health care and education outreach services for individuals and families within Iowa. The contractor shall provide annual reports to the department as specified in the contract.

ITEM 32. Rescind subrule 4.5(3) and adopt the following **new** subrule in lieu thereof:

4.5(3) The University of Iowa Hospitals and Clinics under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

ITEM 33. Amend rule 641—4.7(136A), introductory paragraph, as follows:

641—4.7(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited disorders. These disorders may include birth defects, neuromuscular disorders, metabolic disorders, and all stillbirths. The program also may conduct active statewide surveillance of live births without a reportable congenital or inherited disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited disorders will be conducted for the period of time that adequate financial support is available.

ITEM 34. Amend paragraphs **4.7(1)"a"** and **"b"** as follows:

a. Birth defects shall be defined as any major structural abnormality or metabolic disorder that may adversely affect a child's health and development. The abnormality or disorder must be diagnosed or its signs and symptoms must be recognized within the first ~~year~~ two years of life.

b. Neuromuscular disorders shall be defined as Duchenne, ~~and~~ Becker, congenital, distal, Emery-Dreifuss, fascioscapulohumeral, limb-girdle, myotonic, and oculopharyngeal muscular dystrophies.

ITEM 35. Rescind and reserve paragraph **4.7(1)"c."**

ITEM 36. Amend paragraphs **4.7(2)"a"** and **"b"** as follows:

a. Congenital disorders, including birth defects, occurring in Iowa are reportable conditions, and records of these disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Congenital disorders surveillance shall be performed in order to determine the occurrence and trends of such disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for congenital disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital disorders and their families.

b. Records for ~~selected~~ neuromuscular disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. ~~Selected neuromuscular disorders include Duchenne and Becker muscular dystrophies. Selected neuromuscular~~ Neuromuscular disorders surveillance for individuals of all ages shall be performed in order to determine the occurrence and trends of the selected neuromuscular disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys through annual long-term follow-up, and to assist in the planning for and provision of services to ~~children~~ individuals with selected neuromuscular disorders and their families.

ITEM 37. Rescind and reserve paragraph **4.7(2)"c."**

ITEM 38. Reserve rules **641—4.8** to **641—4.10**.

ITEM 39. Adopt the following **new** heading and rules 641—4.11(136A) to 641—4.14(136A):

CENTER FOR CONGENITAL AND INHERITED DISORDERS ADVISORY COMMITTEE (CIDAC)

641—4.11(136A) Purpose. CIDAC represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and congenital disorders.

641—4.12(136A) Duties of the committee. CIDAC shall perform the following duties:

4.12(1) Make recommendations about the design and implementation of the center's programs, including but not limited to:

a. The Iowa newborn screening program;

b. The regional genetics consultation service;

c. The maternal prenatal screening program;

d. The neuromuscular and related genetic disorders program; and

e. The Iowa registry for congenital and inherited disorders.

4.12(2) Support the development of special projects and conferences regarding genetic and genomic health care services and issues.

4.12(3) Advocate for quality genetic and genomic health care services for all residents in the state of Iowa.

641—4.13(136A) Membership. Membership will be comprised of representatives of professional groups, agencies, legislators, parents, consumers, and professional health care providers.

4.13(1) CIDAC shall be comprised of regular, ex officio, and honorary members.

a. Potential regular members are considered from interest groups, consumer organizations, and genetic and genomic health care service providers. Two parent representatives and two consumer representatives shall serve as regular members of CIDAC.

b. The number of regular members shall not be fewer than 15 or more than 25.

c. No more than 30 percent of regular members shall be representatives of or employed by programs that are contractors of the center for congenital and inherited disorders in the Iowa department of public health.

d. Honorary members will be comprised of two legislators, one state senator and one state representative, and others deemed appropriate by the director.

e. Ex officio members are nominated by virtue of their positions held and the organizations they represent and are appointed by the director. These members provide expert information and consultation to CIDAC.

4.13(2) Every effort will be made to have gender balance and broad geographic representation on the advisory committee.

4.13(3) The director will appoint regular and honorary committee members for three fiscal years. Reappointment of regular and honorary members shall be at the discretion of the director.

641—4.14(136A) Meetings.

4.14(1) Meetings of the committee will be held as necessary and at the call of the director or the chairperson. There shall be a minimum of four meetings per year.

4.14(2) All meetings are open to the public in accordance with the open meetings law, Iowa Code chapter 21.

4.14(3) A majority of the total number of regular members (50 percent plus one member) shall constitute a quorum. There must be a quorum of the regular members in attendance at a meeting for action to be taken.

4.14(4) Action can be taken by a vote of the regular members. Ex officio and honorary members are not eligible to vote.

4.14(5) Regular members who represent programs that are contractors of the center for congenital and inherited disorders in the department are expected to refrain from imposing undue influence on regular members and to recuse themselves from voting on issues which directly affect the operation of their programs.

4.14(6) Meeting attendance.

a. Attendance at a meeting is defined as presence at the meeting site in person, through the Iowa communications network (ICN), through webinar or web meeting, or via telephone.

b. Attendance by the regular member or the regular member's designee shall be expected at all meetings.

(1) A designee of similar standing must be able to reasonably fulfill the member's role on the committee in discussions.

(2) Designees are not eligible to vote.

c. Regular members, not designees, must attend at least two meetings per fiscal year to remain in good standing.

d. A regular member who misses more than three meetings in a fiscal year shall be deemed to have submitted a resignation.